# Clinical Trials Data EGFR - Document 31

# Identification of Gene Expression Signature for Panitumumab Sensitivity in Untreated Locally Advanced SCCHN

## Clinical Trial: https://clinicaltrials.gov/study/NCT01305772

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Untreated, suspected or histologically documented locally advanced clinical stage III or IVa-b(M0)SCCHN, no evidence of distant metastases. Prior surgery with diagnosis of SCCHN acceptable\n2. Candidate for definitive surgery or radiation based therapy.\n3. Fresh frozen tumor tissue must be available for genomic analysis and must pass RNA Quality Control prior to research PET/CT #1 and/or initiating panitumumab\n4. Measurable or evaluable disease\n5. Eastern Cooperative Oncology Group (ECOG) 0-1\n6. \u226518 years of age\n7. Adequate organ function\n\n 1. neutrophil count (ANC or AGC) \u22651.5 x 109/L\n 2. Platelet count \u226575 x 109/L\n 3. Hemoglobin \u22659.0 g/dL\n 4. Creatinine \u22641.5x upper limit of normal (ULN)\n 5. Hepatic enzymes (AST, ALT)\u22642.5x ULN, Total Bilirubin \\<1.5x ULN\n 6. Magnesium \u2265 Lower limit of Normal (LLN)\n8. Negative serum pregnancy test \u22647 days before starting panitumumab (for women of childbearing potential only)\n9. Competent to comprehend, sign, and date a written informed consent form\n10. Sexually active males \\& females of reproductive potential must agree to use adequate method of contraception during treatment \\& for 6 months after study drug stopped\n\nExclusion Criteria:\n\n1. History of other malignancy within past 2 years, except:\n\n 1. Malignancy treated with curative intent and with no known active disease\n 2. Adequately treated non-melanomatous skin cancer or lentigo maligna with no evidence of disease\n 3. Adequately treated cervical carcinoma in situ with no evidence of disease\n 4. Prostatic intraepithelial neoplasia with no evidence of prostate cancer\n2. Primary tumor of the nasopharynx (nasopharyngeal cancer), sinuses, salivary gland, or skin. (Squamous cell carcinoma arising in/near nasopharynx is eligible)\n3. Prior radiotherapy in planned field if it prevents standard radiotherapy dose and field\n4. Prior radiation for head \\& neck cancer\n5. Prior anti-EGFR antibody therapy (e.g., cetuximab) or treatment with small molecule EGFR inhibitors (e.g., gefitinib, erlotinib, lapatinib)\n6. Prior anti-cancer treatment with: chemotherapy, hormonal therapy, immunotherapy, experimental or approved proteins/antibodies within the past 5 years.\n7. Prior systemic chemotherapy for study cancer\n8. Investigational agent or therapy \u226430 days before enrollment and/or have not recovered from such side effects\n9. Continued chronic use of immunosuppressive agents during the clinical trial period (e.g., methotrexate and cyclosporine), corticosteroids are allowed\n10. Clinically significant cardiovascular disease (including myocardial infarction (MI), unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) \u22646 months before enrollment\n11. History of interstitial lung disease e.g., pneumonitis or pulmonary fibrosis or evidence of interstitial lung disease on baseline chest CT scan. Patients with CT scan findings consistent with lung scarring from chronic obstructive pulmonary disease (COPD) or previous infection are eligible\n12. History of any medical or psychiatric condition or laboratory abnormality that in the opinion of the investigator may increase the risk associated with the study participation or investigational product(s) administration or may interfere with the interpretation of the results\n13. Unwilling or unable to comply with study requirements\n14. Pregnant or breast feeding, or planning to become pregnant within 6 months after the end of treatment\n15. Known positive test(s) for HIV infection\n16. Major surgery within 2 weeks of enrollment. Staging endoscopy with biopsy/tonsillectomy for head \\& neck cancer, tracheostomy, and/or gastrostomy tube placement eligible one day after procedure. May consent to tissue collection biopsy pre-endoscopy/minor surgery and then begin protocol therapy one day after procedure.\n17. Known allergy/hypersensitivity to any component of the study treatment(s)\n18. Infection requiring intravenous antibiotics for any uncontrolled infection \u226414 days prior to enrollment\n19. Subjects on anticoagulant therapy. Aspirin and other anti-platelet agents will not be defined as anticoagulant therapy for this study",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a EGFR gene mutation be eligible for the clinical trial?

Answer:  
This trial does \*not\* exclude patients based on EGFR mutation status. It \*requires\* fresh frozen tumor tissue for genomic analysis. This suggests they are \*looking\* at genomic markers like EGFR, but having the mutation isn't an explicit inclusion or exclusion criterion. Therefore, a patient with an EGFR mutation \*could\* be eligible if they meet all the other inclusion criteria and none of the exclusion criteria.